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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/701,845 11/05/2003 Juan Bautista Mario Lucio Magri 3143/1 7788 EXAMINER 7590 09/20/2004 Adams Evans P.A. KOSSON, ROSANNE 2180 Two Wachovia Center ART UNIT PAPER NUMBER Charlotte, NC 28282 1651

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/701,845	LUCIO MAGRI, JUAN BAUTISTA MARIO
	Examiner	Art Unit
	Rosanne Kosson	1651
The MAILING DATE of this communi Period for Reply	cation appears on the cover sheet with	the correspondence address
A SHORTENED STATUTORY PERIOD FOTHE MAILING DATE OF THIS COMMUNION - Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this community of the period for reply specified above, the maximum states of the period for reply is specified above, the maximum states of the period for reply within the set or extended period for	CATION. of 37 CFR 1.136(a). In no event, however, may a repunication. of days, a reply within the statutory minimum of thirty (tutory period will apply and will expire SIX (6) MONTH will, by statute, cause the application to become ABAI	ly be timely filed (30) days will be considered timely. 1S from the mailing date of this communication.
Status		
1) Responsive to communication(s) filed on <u>30 August 2004</u> .		
2a) This action is FINAL . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1-4 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5)⊠ Claim(s) <u>1 and 2</u> is/are allowed.		
6)⊠ Claim(s) <u>3 and 4</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restrict	ion and/or election requirement.	
Application Papers		
9) The specification is objected to by the	Examiner.	
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12)⊠ Acknowledgment is made of a claim fo	or foreign priority under 35 U.S.C. 8.1	19(a)-(d) or (f)
a) ⊠ All b) □ Some * c) □ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Sum	pman/ (PTO 412)
2) Notice of Draftsperson's Patent Drawing Review (PT	O-948) Paper No(s)/N	//ail Date
3) Information Disclosure Statement(s) (PTO-1449 or P Paper No(s)/Mail Date	TO/SB/08) 5) Notice of Infor 6) Other:	rmal Patent Application (PTO-152)
U.S. Patent and Trademark Office	o) [_] Other;	
PTOL-326 (Rev. 1-04)	Office Action Summary	Part of Paper No./Mail Date 20040908

DETAILED ACTION

The amendment filed on August 30, 2004 has been received and entered. The text of those sections of Title 35, U.S. code, not included in this action can be found in a prior office action.

Claims 1-4 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 1-4, the word "preferably" in claim 1 renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. It is unclear whose preference and when the preference is to be exercised. It is also unclear whether or not the claim requires growth of *Rhizobium japonicum* at 28°C. Applicant may wish to delete the word "preferably" so that the claim is no longer indefinite. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claim 3 as amended is rejected under 35 U.S.C. 102(b) as being anticipated by ATCC Bacteria and Bacteriophages, 19th Ed., P. Pienta et al, eds., pp. 72 and 301, American Type Culture Collection, Rockville, MD, 1996. Claim 3 as amended reads on a biologically pure culture of *Rhizobium japonicum*, because the comprising language of claim 1 encompasses steps of purifying the microorganism. Thus, the resulting product is an inoculating composition for use with leguminous plants containing just *R. japonicum*. This bacterium is commercially available from, i.a., the ATCC, as shown by the enclosed catalogue excerpt. Accordingly, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. (U.S. 3,168,796), Kuykendall et al. (Applied and Environmental Microbiology 22(4):511-519, 1976) and Bergey's Manual (Bergey's Manual of Determinative Microbiology, 8th Ed., R.E. Buchanan & N.E. Gibbons, eds., pp. 262-264,The Williams & Wilkins Co., Baltimore, 1974) in view of Guri et al. (U.S. 5,750,402) and Jung et al. (U.S. 4,755,468). Scott discloses a general use culture medium comprising grown *Rhizobium japonicum* and disaccharides, as well as a method for making for this

medium, and notes that the Rhizobium may be grown using standard procedures well known in the art (see column 5, lines 13-36, and column 5, line 73, to column 6, line 15). Kuykendall also discloses a general use culture medium comprising grown *Rhizobium japonicum* and sterilized sugars, including maltose, as well as a method for making for this medium (see p. 512, Materials and Methods, and p. 516, 2d paragraph). Kuykendall notes that the Rhizobium grew equally well on 10 different carbon sources, including five different sugars. Indeed, all species of Rhizobia are known to utilize a wide range of carbohydrates (see <u>Bergey's Manual of Determinative Bacteriology, 8th Ed.</u>, pp. 262-264). Guri discloses that potassium sorbate is a known microbicide that can be used with plant growth media (see column 3, lines 53-59, and column 4, lines 45-65) and cites, i.a., the Merck Index, which lists potassium sorbate as a mold and yeast inhibitor. Jung discloses a plant growth medium comprising grown *Rhizobium japonicum* and that fungicides may be added to the medium without altering the bacterial cells (see column 6, lines 7-13, and column 7, lines 23-25).

Thus, one of ordinary skill in the art would be motivated to modify the medium of Scott or Kuykendall to include the fungicide potassium sorbate because, as noted in Guri, plant culture media are subject to contamination by unwanted organisms. Adding an antimicrobial agent helps maintain sterile conditions to allow for proper growth of the plant to be inoculated into the medium (see column 1, Field of the Invention). The skilled artisan would further note from Jung that a fungicide may be used in a plant growth medium containing *Rhizobium japonicum* without harming the Rhizobium.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. (U.S. 3,168,796), Kuykendall et al. (Applied and Environmental Microbiology 22(4):511-519, 1976) and Bergey's Manual (Bergey's Manual of Determinative Microbiology, 8th Ed., R.E. Buchanan & N.E. Gibbons, eds., pp. 262-264, The Williams & Wilkins Co., Baltimore, 1974) in view of Guri et al. (U.S. 5,750,402) and Jung et al. (U.S. 4,755,468) as applied to claim 3 above, and further in view of Kosanke et al. (U.S. 5,695,541) or Gleddie et al. (U.S. 5,586,411). As discussed above, claim 3 is considered obvious over Scott/Kuykendall/Bergey's Manual /Guri and Jung. None of the cited references discloses the use of peat in a Rhizobium-containing medium, as recited in claim 4. Kosanke, however, discloses that it is known in the relevant art to mix living rhizobial cultures with peat as a carrier when the rhizobial cultures are to be used as an inoculant for leguminous plants. Peat supplies moisture to the rhizobia to maintain them in a living state (see column 1, lines 24-33). Thus, the skilled artisan would be motivated to add peat to a Rhizobium-containing growth medium, as taught by Kosanke, in order to maintain the viability of the rhizobium and improve the properties of the growth medium. Gleddie discloses that, although peat is the carrier of choice for the rhizobial inoculant industry, peat that has been sterilized prior to mixing with rhizobial cells provides the highest quality, most stable and most efficacious rhizobial inoculant. Using peat that has not been presterilized can introduce microbial contaminants that adversely affect the properties of the inoculant (see column 1, line 56, to column 2, line 11). As a result, the skilled artisan would be motivated to use presterilized peat in preparing a Rhizobium-containing growth medium, as taught by Gleddie, in order to

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produce a high-quality medium free of contaminants. Therefore, a holding of obviousness is required.

Response to Arguments

All of Applicant's arguments have been fully considered but are not persuasive of error. Applicant states that the difference between the claimed invention and the prior art is that, in the instant invention, the Rhizobium is allowed to grow for two days in the presterilized culture medium and then additional sugars, maltose and lactose, are added. The additional sugars are not added for further growth but to protect the Rhizobium membrane.

Applicant's arguments are persuasive with respect to claims 1 and 2, the process claims, but not with respect to claims 3 and 4, the composition claims. Firstly, claim 3 as amended is directed to a composition comprising Rhizobium prepared by the method of claim 1. Consequently, the composition may also contain components or by-products of the culture medium or maltose or lactose or potassium sorbate. The order of addition of the composition's elements to the composition is not relevant. The composition of Scott, or the composition of Scott as modified by the teachings of Guri to add the preservative potassium sorbate, reads on the claimed composition. Secondly, Scott discloses that in the method of preparing its inoculation medium, the Rhizobium is grown for 5-7 days before the disaccharides are added to the live culture, in order to protect the cells, which are then ready for drying (see column 5, line 13, to column 6, line 18). Thus, the order of steps disclosed in Scott is the same as Applicant's.

Regarding Applicant's assertion that the composition of claim 3 shows unexpected results because it may be stored at ambient temperature for 18 months versus 15 days at room temperature or 30 days at cold temperatures in the prior art, it is unclear to which prior art Applicant refers. The inoculation composition of Scott may be mixed with seeds and stored in seed warehouses for months to two years (see column 3, line 73, to column 4, line 2). Certainly, adding a widely used preservative such as potassium sorbate to an inoculation composition will improve the storage properties compared to inoculation compositions without preservatives. Without a clear basis for comparison, Applicant's results of storage properties cannot be considered unexpected.

Claim 4 as amended recites a composition comprising *R. japonicum* and peat. The peat is present at a concentration of 5-20% by weight. Again, no purification steps are excluded from the process-of-making claims that produce the composition of claim 4. The composition may also contain maltose or lactose or potassium sorbate, and the order of addition of the composition's elements to the composition is not relevant. Consequently, the composition of Scott as modified by the teachings of Gleddie to add pre-sterilized peat, or the composition of Scott as modified by the teachings of Guri to add the preservative potassium sorbate and the teachings of Gleddie to add pre-sterilized peat, reads on the claimed composition. Applicant purports that the composition of claim 4 shows unexpected properties because it is prepared with peat that is sterilized with the culture medium, rather than peat sterilized separately from the culture medium. When the peat is sterilized with the culture medium, the viability count increases by about nine-fold, and the number of nodules per plant increases by about

two-fold (Table III). Applicant also shows that, compared to a growth medium without peat, adding peat to the culture medium increases the viability count by about two to five-fold and the number of nodules per plant by about two to three-fold (Tables I and II). Thus, particularly given the degree to which bacteria can multiply (several orders of magnitude), the increases shown in Table III do not amount to unexpected results that distinguish the composition of claim 4 from the prior art.

Thus, a holding of obviousness for claims 3 and 4 is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

' FRANCISCO PRATS PRIMARY EXAMINER Application/Control Number: 10/701,845

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Rosanne Kosson Examiner Art Unit 1651

2004-09-09

PRIMARY EXAMINER